

Remarks

Amendments to claims

Claim 1 is amended to incorporate the feature of canceled Claim 8, and is further reformatted so that the characterizing features of the promoter are recited together.

Claims 9 and 15 are amended to change claim dependency.

Newly added claim 21 further defines the mature plant as being “fruit-bearing”. Support for the claim exists in claim 15 and throughout the specification.

Support for new claims 22 and 23 is on page 32 of the specification, which describes experiments that demonstrate that the Mel7 promoter can drive reporter gene expression in non-melon fruit-bearing species such as apple, pear, and tomato.

Status of claims

Upon entry of the present amendment, claims 1, 5, 7, 9-12, 15, 19, and 20-23 are pending. The Advisory Action indicated that claim 5 would be allowable if presented in independent form, and that the remaining claims stand rejected under 35 U.S.C. § 112, 1st paragraph for lack of compliance with the written description and enablement requirements.

Written description rejection

In the Advisory Action, continuation of 5, the examiner maintains the written description rejection because the specification “does not present the sequences of any fragments within nucleotides 156-1708 that retain its promoter activity” and that the definition for “promoter” in the specification “only provides a function, without correlating it to a structure.”

The written description requirement guidelines state:

The examiner has the initial burden, after a thorough reading and evaluation of the content of the application, of presenting evidence or reasons why a person skilled in the art would not recognize that the written description of the invention provides support for the claims (Fed. Reg., Vol 66, No. 4, January 5, 2001, p. 1105).

The examiner has not explained why one skilled in the art would not recognize the specification as providing a description of the invention defined by the claims. Thus, a proper rejection under the written description requirement has not been made.

In evaluating whether there is adequate written description, the written description guidelines indicate that the level of skill and knowledge in the art should be considered.

(Fed. Reg., supra, p. 1106). There is a high level of skill and knowledge in the art concerning plant regulatory regions. Exhibits A-E provided herewith are a sampling of abstracts that demonstrate that at the time of the applicants' invention, it was common practice to identify sub-fragments of a promoter region that retain promoter activity. The applicants have disclosed a 1552 nucleotide sequence (nucleotides 156-1708 of SEQ ID NO:42) derived from melon and have shown that the sequence is able to direct transgene expression in several fruit species (p. 32 of specification). The description provided in the specification of what constitutes a "promoter" includes segments of the specifically disclosed sequences that retain promoter function (p. 7, lines 6-9). Thus, one skilled in the art will appreciate that the applicants considered as being within the scope of their invention segments of the 1552 nucleotide sequence that retain fruit-associated promoter activity.

The written description guidelines explain that in some situations, disclosure of a single species may adequately support a claimed genus. If "one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed", then the written description requirement is satisfied (Fed. Reg., supra, p. 1106). With regard to claim 1, this is not a situation where the genus encompasses widely variant species, having different sequences, such as would be the case if the applicants were claiming any promoter sequence capable of inducing fruit-associated expression that contains 65% identity with the disclosed Mel7 promoter region (e.g. see claim 1 of U.S. Pat. No. 6,177,613 attached as Exhibit F). Instead, every member of the genus will comprise the same nucleotide sequence contained within SEQ ID NO:42 that functions to drive transgene expression in fruit. The only difference between members of the species is the amount of extraneous sequence not responsible for the fruit-associated promoter activity. Clearly, the applicants were in possession of the necessary common attributes or features of the elements possessed by the members of the genus. Thus, the written description requirement is satisfied.

For the above reasons, it is believed that the written description rejection under 35 U.S.C. § 112, 1st paragraph should be withdrawn.

Enablement rejection

In the Advisory Action, continuation of 5, the examiner maintains the enablement rejection because "the specification does not provide any guidance as to the sequences within the promoter of bases 156-1708 of SEQ ID NO:42 that are essential to its tissue-specific activity." However, the examiner has not provided any reasoning as to why such

guidance must be provided in order to enable the claims. Thus, a proper enablement rejection has not been raised (see MPEP §2165.04 on p. 2100-183, 1st paragraph). Further, in response to the applicants' previous argument that routine experimentation, such as deletion analysis, can be used to identify fragments of the 1552 nucleotide sequence that retain fruit-associated promoter activity, the examiner relied on Genentech v. Novo Nordisk for teaching that "the specification, not the knowledge of one skilled in the art must supply the *enabling aspects* of the invention." (Advisory action, last sentence of continuation of part 5; emphasis added) However, this is misleading – the Genentech case does not use the phrase "enabling aspects", but instead refers to "novel aspects". With regard to the amount of disclosure required to enable a claimed invention, it is well established that "a patent need not teach, and preferably omits, what is well known in the art" (MPEP §2164.01).

A claim satisfies the enablement requirement if the disclosure contains "sufficient information regarding the subject matter of the claims as to enable one skilled in the pertinent art to make and use the claimed invention" without undue experimentation (MPEP §2164.01). The factors to consider in an enablement determination include: (A) the breadth of the claims; (B) the nature of the invention; (C) the state of the prior art; (D) the level of one of ordinary skill; (E) the level of predictability in the art; (F) the amount of direction provided by the inventor; (G) the existence of working examples; and (H) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. These factors are addressed below:

(A) Breadth of claims: The breadth of the claims is relatively narrow. The isolated nucleic acid molecule of claim 1 comprises a promoter contained within SEQ ID NO:42 that directs fruit-associated expression of a heterologous protein. Thus, every embodiment of the claim contains an identical promoter sequence, and the only difference between the different embodiments will be the amount of sequence from SEQ ID NO:42 that is unnecessary for the activity.

(B – D) Nature of the invention, state of the prior art, and level of one of ordinary skill: MPEP §2164.05(a) addresses the significance of these three factors, with "nature of the invention" being the "backdrop to determine the state of the art and the level of skill possessed by one skilled in the art." The nature of the invention concerns plant promoters. At the time of the applicants' filing date, the state of the art and the level of skill in the art were high. Plant promoters were widely studied. Once a regulatory region was identified as having a particular promoter activity, it was a routine matter, as evidenced by the state of the prior art exemplified by Exhibits A-E, to make and test for fragments of that regulatory region that retained the promoter activity. Any skilled molecular biologist, taking the

sequence and functional data provided in the applicants' specification, could perform a number of standard experiments such as 5' deletion analysis, DNA footprinting, or others, to identify smaller elements that confer similar functionality. This does not constitute undue experimentation.

(E) Level of predictability in the art: It is highly predictable that one skilled in the art will be able to make fragments of nucleotides 156-1708 of SEQ ID NO:42 that retain fruit-associated promoter activity.

(F-G) Amount of direction provided & existence of working examples: The specification provides the sequence of the promoter region of the Mel7 gene, and describes straight-forward assays for assessing promoter activity in various fruit-bearing plants (see Example 4, p. 31). Thus, sufficient direction is provided should one skilled in the art wish to practice the invention of claim 1 using a promoter fragment from SEQ ID NO:42 that is not identical to the embodiment described in the working examples.

(H) Quantity of experimentation needed: The quantity of experimentation needed to practice the scope of the claimed invention is minimal. As discussed above, having identified a 1552 nucleotide sequence having fruit-associated promoter activity, one of ordinary skill in the art can readily identify fragments of that sequence that retain the fruit-associated promoter activity.

For the above reasons, the claimed invention is supported by an enabling disclosure, and the rejection under 35 U.S.C. § 112, 1st paragraph should be withdrawn.

Closing remarks

It is believed that all of the rejections are overcome, and that the claims are in condition for allowance. The examiner is encouraged to telephone the undersigned to discuss any further issues that may need resolution prior to allowance.

Respectfully submitted,

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